**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA<br><br>v.<br><br>BARRY J. CADDEN, et al.<br><br>*Defendants*. | ) | Criminal Action No. 14-10363-RGS |

**SUPPLEMENTAL MOTION REGARDING EVIDENCE OF PATIENT HARM RELATED TO METHYLPREDNISOLONE ACETATE**

In an order dated May 7, 2018, this Court granted remaining defendants' motion to exclude evidence of patient harm related to methylprednisolone acetate (MPA) based on Fed. R. Evid. 403. Dkt. 1495. The Court's order noted that "the proposed evidence of patients' deaths and injuries entails a substantial risk that jurors will decide the case on an improper basis rather than on the evidence presented," and observed that "[t]he government has more than ample alternative means of showing that the alleged representations made by defendants as to the hygienic conditions NECC's clean rooms, the freshness of its drug ingredients, and the integrity of its sterility testing, were false without resorting to evidence of patient deaths and injuries." *Id*. at 15–16. The remaining defendants—Joseph Evanosky, Gene Svirskiy, Christopher Leary, Sharon Carter, Alla Stepanets, Gregory Conigliaro, Kathy Chin, and Michelle Thomas—now respectfully ask the Court to specifically enforce this order by prohibiting during trial the use of words that indicate patient harm occurred in connection with methylprednisolone acetate (MPA) from NECC, including but not limited to the word "outbreak;" by requiring the government to instruct all of its witnesses that such evidence of patient harm has been excluded from this trial

and is not to be mentioned in front of the jury; and by directing the government to review every page of each of its exhibits to ensure that none contains any reference to MPA-linked patient harm, including use of words like "outbreak." Because just one stray mention of death or harm could cause extreme and irreversible undue prejudice, such an order will serve as a necessary prophylactic measure against inadvertent references to the extraordinarily prejudicial evidence the Court has excluded, and help prevent a possible mistrial.

As this Court recognized in its order, references to an "outbreak" in connection with MPA made at NECC are by definition evidence of patient harm. *See, e.g.*, Dkt. 1495, at 12 (citing as an example of impermissible patient harm testimony that of Dr. Benjamin Park of the CDC, who described the NECC-linked fungal meningitis as "the largest healthcare outbreak in the United States' history . . . . the only thing that I can compare it to, just in terms of the speed and the importance of it, was really the Ebola outbreak."). *See also Outbreak*, Oxford English Dictionary (3d ed. 2004) (defining "outbreak" as "[a] sudden increase in the incidence of a disease"). Any reference to an NECC related "outbreak" is thus covered by this Court's order prohibiting evidence of MPA-related patient harm, and the remaining defendants seek the Court's help in vigilantly guarding against the admission of such statements at trial.[1]

Remaining defendants bring this motion in light of the government's recently filed witness list and proposed 915-item exhibit list served on defendants, which are rife with MPA evidence, witnesses who testified about the meningitis outbreak and MPA-related patient harm at the Cadden and Chin trials, and documents containing references to "the outbreak" and patient harm. For instance, the government has listed as a witness Dr. John Cuclasure, a physician who injected his patients with MPA from NECC and gave extensive, emotional testimony at the

[1] To be sure, the remaining defendants are not currently contesting that evidence of contamination may be relevant to the charged RICO mail fraud conspiracy and thus are not seeking to prohibit references to "contamination," for example.

Cadden and Chin trials about patients getting sick and dying. Another government witness is Dr. Mary Brandt, who from 2006 to 2016 was head of the CDC's Mycotic Diseases Branch. Cadden Tr. Day 37, 84:11-16. Dr. Brandt testified at both the Cadden and Chin trials, discussing the outbreak and her department's response to it, noting that patients had mysteriously died of rare strokes, *see id.* at 91-92, and providing extensive descriptions of subjects such as testing patient samples for fungal contamination. The word "outbreak" was used 25 times during her direct testimony in the Cadden trial, in both her answers and in government questions. *E.g. id*. at 94:19-20 ("Everybody in the branch, all of our laboratory staff were working on this outbreak. We stopped all other work."). Similarly, FDA witnesses who inspected NECC in the fall of 2012 also discussed the outbreak in the course of explaining why the inspection occurred and how it proceeded. *E.g.*,Testimony of Stacey Degarmo, Cadden Tr. Day 32, 37-38 (stating that when she was assigned to inspect NECC, she was told to listen to a conference call "to give us a little bit of background about what was going on so far, the information that we knew at that point about the outbreak" and learned on the call that " there had been seven patients that had been diagnosed with a fungal meningitis. They had all received spinal injections."). With this kind of background, and given human nature, it is easy to see how any of these witnesses—to name just a few examples—might accidentally refer to the outbreak in the course of their testimony in this trial.

On a related note, defendants have also identified a number of exhibits on the government's list that mention the NECC-linked meningitis and patient harm. For instance, Exhibit 794 is a chart entitled "summary of CDC results of biological samples from fungal meningitis," which identifies patient names, the fact that the patient was infected, the bacteria at issue, and more, with deceased victims' names printed in red. Exhibit 705 is an email thread with

the subject line "Aspergillus Meningitis/New England Compounding Center" sent to Mutahar Shamsi, a government witness; it includes a message stating, "[t]here may be many more cases out there that have not been recognized, and with a long incubation period possible, more cases to come" and "the attack rate could be 1 per 100 to 1 per 200 patients…" Exhibit 727, a document the government refers to on its exhibit list as "re CDC update on meningitis outbreak II," is similar, with the subject line "Aspergillus meningitis following injection from compounding pharmacy" and text noting that the Tennessee Department of Health reported "Aspergillus meningitis in a patient following a steroid (methylprednisolone) injection from a compounding pharmacy in Massachusetts." These are just representative examples. There are more. This type of evidence is squarely prohibited by this Court's order on the motion to exclude and should be removed from the government's exhibit list. Moreover, it highlights the risk that prohibited evidence will find its way into the trial without further action by the Court.

The government has an affirmative responsibility to comply with the Court's order, and the witnesses and exhibits listed give defendants pause that the government intends to proactively seek to meet that burden. It should not fall to defendants' counsel to ferret out every government exhibit that runs afoul of the Court's order, or jump up constantly at trial to object or move to strike—particularly when such measures can never hope to undo the prejudice that will result if the jury is exposed to the patient harm evidence the Court has excluded. Therefore, the remaining defendants request that the Court prohibit during trial the use of words that indicate patient harm occurred in connection with methylprednisolone acetate (MPA) from NECC, including but not limited to the word "outbreak;" require the government to instruct all of its witnesses that evidence of MPA-related patient harm has been excluded from this trial and is not to be mentioned in front of the jury; and direct the government to review each page of each

exhibit to remove all references to MPA-related patient harm, including the use of words such as "outbreak."

Respectfully submitted,

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Dated: September 17, 2018

**CERTIFICATE PURSUANT TO L.R. 7.1 AND 112.1**

I hereby certify that I conferred with Assistant United States Attorney Amanda Strachan in a good faith effort to resolve or narrow the issues raised by this motion pursuant to L.R. 7.1 and 112.1.

/s/ Dana M. McSherry

Dana M. McSherry

**CERTIFICATE OF SERVICE**

I, Dana M. McSherry, hereby certify that this document was filed on September 17, 2018, via the ECF system, and was sent electronically on that date to the parties' counsel of record.

/s/ Dana M. McSherry

Dana M. McSherry